



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/643,006 | 08/18/2003 | Eric G. Lovett | GUID.060PA | 2975 |
| 51294 7590 01/23/2008 HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425 | | | EXAMINER NGUYEN, HUONG Q | |
| | | | ART UNIT 3736 | PAPER NUMBER |
| | | | MAIL DATE 01/23/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/643,006 | Applicant(s) LOVETT ET AL. | |
| | Examiner Helen Nguyen | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 10-15, 17-26, 28-30, 48, 49, 51, 52, 54, 55, 58, 60 and 62-85 is/are pending in the application.
- 4a) Of the above claim(s) 81-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10-15, 17-26, 28-30, 48, 49, 51, 52, 54, 55, 58, 60 and 62-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species corresponding to Figure 1B in the reply filed on 11/5/2007 is acknowledged.
2. Claims 5, 8-9, 16, 27, 31-47, 50, 53, 56-57, 59, and 61 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in the reply filed on 11/5/2007.
3. It is noted that Applicant has not withdrawn Claims 81-85 as identified in the previous restriction requirement as belonging to the nonelected species corresponding to Figure 1A. Therefore, Claims 81-85 are also accordingly withdrawn as being drawn to a nonelected species.
4. **Claims 1-4, 6-7, 10-15, 17-26, 28-30, 48-49, 51-52, 54-55, 58, 60, and 62-80** remain pending.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-4, 10-15, 17-26, 28-30, 48-49, 51-52, and 62-80** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (US Pat No. 5902250) in view of Cho et al (US Pub No. 20050119711).

7. In regard to **Claims 1-3, 12-15, 48-49, 51, 62-65, 72, and 75**, Verrier et al disclose a method and apparatus for classifying sleep states comprising:

a detector system comprising sensors 12, 14 for detecting conditions related to sleep, the sleep-related conditions comprising a condition associated with a sleep-wake status of a patient such as patient activity or head movement (Col.5: 34-35) and a condition associated with REM sleep such as eyelid movement (Col.11: 29-35);

a classification system 34 for classifying one or more sleep states based on the detected conditions (Col.8: 39-41).

8. However, Verrier et al do not disclose classifying the one or more sleep states is performed at least in part implantably. It is noted that Verrier et al do disclose the invention also used for monitoring breathing for the detection of sleep-related conditions. Cho et al disclose an effective implantable analogous device for the detection of sleep-related breathing conditions to provide the advantages of constant monitoring without the disadvantages associated with user-related use (§0010). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the invention of Verrier et al perform the classifying of one or more sleep states at least in part implantably as taught by Cho et al to improve the device by allowing constant monitoring without requiring user involvement for use.

9. In regard to **Claims 4 and 52**, Verrier et al in combination with Cho et al disclose the method and apparatus for detecting the sleep-wake status of the patient by patient activity through sensor 14 but do not specifically disclose detecting the sleep-wake status using an accelerometer. However, Verrier et al do disclose that any suitable sensor for detecting

movement can be used in place of sensor 14 (Col.7: 18-20). Because it is widely known that an accelerometer detects movement, it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the sleep-wake status of the patient using an accelerometer as an equally as effective sensor for detecting the patient activity and thus sleep-wake status.

10. In regard to **Claims 10-11**, Cho et al disclose detecting the conditions related to sleep comprises detecting body posture or torso orientation (§0045).

11. In regards to **Claim 17**, Verrier et al and Cho et al disclose the method and apparatus for classifying the one or more sleep states on a real-time basis.

12. In regard to **Claims 18-21, 66-68, and 76**, Verrier et al and Cho et al disclose the invention above but do not disclose the invention for providing sleep state informed therapy. Cho et al teach that the implantable device for detecting sleep-related conditions provides therapy (§0016) to effectively treat the patient when certain conditions are detected. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al and Cho et al to provide sleep state informed therapy such as respiratory or cardiac therapy as taught by Cho et al to effectively treat the patient when respiratory or cardiac sleep-related conditions are detected.

13. In regard to **Claims 22, 71, and 77**, Verrier et al disclose using the sleep state classification to perform sleep state informed diagnostic testing.
14. In regard to **Claims 23, 69-70, and 78**, Verrier et al disclose using the sleep state classification to perform sleep state informed testing of therapy parameters (Col.12: 14-16).
15. In regards to **Claim 24**, Verrier et al disclose using the sleep state classification to perform sleep state informed monitoring of patient conditions.
16. In regard to **Claims 25-26 and 79-80**, Verrier et al disclose using the sleep state classification to determine physiological responses of the patient during sleep such as intrinsic responses such as breathing.
17. In regard to **Claims 28-30 and 73-74**, Verrier et al disclose the method and apparatus for classifying the one or more sleep states adaptively comprising learning sleep-related responses of a patient by taking into account different conditions already existing in different patients before classifying the one ore more sleep states. It would also have been obvious to one of ordinary skill in the art to then detect such changes in sleep-related signals over a period of time and learning the sleep-related responses based on the detected changes to continuously update the data for an improved invention that takes into account current patient conditions.

18. **Claims 6-7, 54-55, 58, and 60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al, further in view of Hendricks et al (US Pat No. 6387907).

19. In regard to **Claims 6-7 and 54-55**, Verrier et al in combination with Cho et al disclose classifying REM sleep but do not disclose doing so by sensing muscle tone using an electromyogram sensor. Hendricks et al teach that REM is characterized by the lack of muscle tone, which can be determined through EMG activity (Col.10: 53-61). Since it is well known in the art that an electromyogram sensor senses EMG activity, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al and Cho et al to sense REM sleep through muscle tone using an electromyogram sensor as taught by Hendricks et al as an equally as effective means of classifying REM sleep.

20. In regard to **Claims 58 and 60**, Verrier et al in combination with Cho et al and Hendricks et al disclose the muscle tone sensor (EMG) is mechanically coupled to an implantable device, specifically a housing of the implantable cardiac device, and the classification system is disposed within a housing of the implantable cardiac device.

Response to Arguments

21. Applicant's arguments with respect to **Claims 1-4, 6-7, 10-15, 17-26, 28-30, 48-49, 51-52, 54-55, 58, 60, and 62-80** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN

